K003696

JAN 2 5 2001

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Submitter's Name:

Laurence A. Potter
Dade Behring, Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: November 24, 2000

Name of Product(s):

Stratus® CS STAT Fluorometric Analyzer βhCG TestPak
Stratus® CS STAT Fluorometric Analyzer βhCG CalPak
Stratus® CS STAT Fluorometric Analyzer βhCG DilPak [Test System]

FDA Classification Name: DHA, Human Chorionic Gonadotropin Test System

Predicate Device(s):

Dade Behring Dimension® hCG Flex™ Reagent Cartridge Test System, Cat. No. RF430, 510(k) K970387.

Dade Behring Dimension® hCG Calibrator, Cat. No. RC430, 510(k) K970396.

Device Description(s):

The Stratus® CS ßhCG procedure is a solid-phase, two-site sandwich, fluorometric immunoassay based upon Radial Partition Immunoassay (RPIA) technology. In this procedure, dendrimer-linked monoclonal ßhCG antibody is added to the center portion of a square piece of glass fiber paper in the ßhCG TestPak. The dendrimer binds electrostatically to the glass fibers and immobilizes the capture antibody to the paper. Sample is then added, whereupon ßhCG reacts with the immobilized antibody. After a short incubation, a conjugate, consisting of enzyme-labeled (alkaline phosphatase) monoclonal antibody directed against a distinct antigenic site on the ßhCG molecule, is pipetted onto the reaction zone of the paper. During this second incubation period, the unbound, labeled antibody is radially eluted with a wash solution. By including substrate (4-methylumbeliferyl phosphate) for the enzyme within the wash solution, initiation of enzyme activity occurs simultaneously with the wash. The enzymatic rate of the bound fraction increases directly with the concentration of ßhCG in the sample.

Utilization of two monoclonal antibodies which are specific for distinct antigenic sites on the ß subunit of hCG allows the assay to measures the *total* ßhCG in the sample, *vis*, both the intact hCG dimer and the free ß subunit. Concentration is measured by an optical system that monitors the reaction rate via front-surface fluorescence. All data analysis functions are performed by the microprocessor within the Analyzer and results are reported as mIU/mL. The time to first result, including the onboard whole blood sample processing, is about 14 minutes.

Intended Use(s):

The Stratus® CS βhCG Test System is composed of three individual catalog numbers for commercialization. These include : βhCG TestPak (Cat. No. CBHCG); βhCG CalPak (Calibrator, Cat No. CBHCG-C); and DilPak (Diluent, Cat. No. CBHCG-D).

TestPak: The βhCG method on the Stratus® CS STAT Fluorometric Analyzer is an *in vitro* diagnostic test for the quantitative measurement of the total beta subunit, vis, both the intact hCG dimer and the free β subunit, of the human chorionic gonadotropin hormone in heparinized plasma. βhCG is used for the early detection of pregnancy. This test is not intended for use as a surrogate marker for aiding in the diagnosis or monitoring the treatment of cancer patients.

CalPak: The βhCG Calibrator (βhCG CalPak), Cat. No. CBHCG-C, is an *in vitro* diagnostic product intended to be used for calibration of the βhCG method on the Stratus® CS Analyzer.

DilPak: The βhCG Dilution Pak (βhCG DilPak, Cat No. CBHCG-D), is an *in vitro* diagnostic product intended to be used in conjunction with the βhCG TestPak, Cat. No. CBHCG, on the Stratus® CS Analyzer for the measurement of samples with elevated βhCG levels.

Comparison to Predicate Device:

Item	Stratus® CS βhCG	Dimension® hCG Method
Technology	Two site "sandwich" fluorometric monoclonal antibody immunoassay	Two site "sandwich" colorimetric monoclonal antibody immunoassay
Automation	Fully automated except for manual dilution of samples above 50,000 mIU/mL	Fully automated
Detection	Fluorometric rate measurement (mV/min @ 490 nm)	Colorimetric rate measurement (mV/min @ 577 nm and 700 nm)
Sample Size	75µL	40µL
Measurement Matrix	Whole blood / plasma (heparinized)	serum and plasma
Assay Range	0 – 1250 mIU/mL	1 – 1000 mIU/mL
Calibration Traceability	WHO 3rd IS 75/537	WHO 3rd IS 75/537
Reportable Units	mIU/mL	mIU/mL

Comparison to Predicate Calibrator Device:

Item	Stratus® ßhCG CalPak	Dimension® hCG Calibrator
Intended Use	ßhCG Method Calibration	HCG Method Calibration
Analyte	Human Chorionic Gonadotropin	Human Chorionic Gonadotropin
Matrix	Bovine Serum	Horse Serum
Form	Liquid	Lyophilized
Volume	3 wells in CalPak cartridge @ 150 µL ea.	2.0 mL per vial, reconstituted
Levels	1 level @ 950 mIU/mL	5 levels

Comments on Substantial Equivalence:

Split sample comparison between the Stratus® CS βhCG Test System and the Dimension Human Chorionic Gonadotropin Flex™ reagent cartridge gave a correlation coefficient of 0.9916, slope of 0.94, and an intercept of - 1.53 when tested with 122 clinical patient samples.

Conclusion:

The Stratus® CS βhCG Test System is substantially equivalent in principle and performance to the Dade Behring Dimension® Human Chorionic Gonadotropin Flex™ reagent cartridge test system based on the split sample comparison discussed above.

Laurence A. Potter
Regulatory Affairs and Compliance Manager
Date: November 24, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2001

Mr. Laurence A. Potter
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
Route 896, Glasgow Building 100
PO Box 6101
Newark, Delaware 19714

Re: K003696
Trade Name: Stratus® CS STAT Fluorometric Analyzer βhCG TestPak
Stratus® CS STAT Fluorometric Analyzer βhCG CalPak
Stratus® CS STAT Fluorometric Analyzer βhCG DilPak
Regulatory Class: II
Product Code: DHA, JIT
Dated: November 24, 2000
Received: November 30, 2000

Dear Mr. Potter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

Device Name(s): Stratus® CS STAT Fluorometric Analyzer βhCG TestPak
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Laurence A. Potter
Regulatory Affairs and Compliance Manager

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003696

November 24, 2000

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)